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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KHOLDEBARIN, IMAN K	
ART UNIT	PAPER NUMBER
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,215	QUERLEUX ET AL.	
	Examiner	Art Unit	
	I Kenneth Kholdebarin	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. It is noted that claims 32 and 33 are directed to a method of treating a region of human body and has been considered as independent claim in shorthand form.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the inclusion of legal phraseology, "comprising" in line 2. Further, it has been drafted as one long run-on sentence, much like claim 1, which is improper. The abstract should be narrative and consist of a series of complete sentences forming a single paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Re claim 34: the preamble of the claim, "method of promoting the sale of a product" in lines 1 is not covered within the limitation of claim language. For examination purposes claim 34 and 32 are examined together.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Fink (US 6,770,033).

Re claim 1:Fink discloses analysis apparatus for analyzing the skin, the apparatus comprising: an ultrasound probe (6) arranged to analyze the skin along an axis; and a vibrator (2) arranged to emit at least one shear wave to a region of the skin extending about the axis, wherein the ultrasound probe is arranged to detect a displacement induced in the skin by propagation of the shear wave, (See Figs. 2; col.8, lines 25-30).

Re claim 2: Fink discloses a coupling member / Viscoelastic medium (1) enabling ultrasound waves to be transmitted between the probe and the skin, (See Fig 1; col.4, lines 55-65 – col. 5 line 1-3).

Re claim 10: Fink discloses in Fig.2 where vibrator includes an annular piece defining a contact surface from which the shear wave is emitted to the skin, the annular piece presenting a central bore in which the ultrasound probe extends, (See Fig. 2; col. 5, lines 51-60).

Re claims 13-15: Fink discloses wherein the probe (6) is arranged to emit and receive ultrasound waves at a frequency of 50 MHz, (See col.5; line 46-51).

Re Claims 16 and 17: fink discloses a generator (G in Fig. 1) arranged to deliver a low-frequency signal to the vibrator (2) during the entire analysis period, the signal having a frequency of about 300 Hz, (See col.1 line 46-51).

Re Claim 18: Fink discloses a processor device (CPU) arranged to deliver at least one piece of information from signals picked up by the ultrasound probe, wherein the information represents a mechanical property (displacement of the shear wave) and/or a thickness of at least one layer of the skin (See col. 7; line 25-55).

Re Claim 21: Fink disclose apparatus wherein the processor (CPU) device is arranged to store (Memory M) the signals picked up by the ultrasound probe at various successive time points, (See Fig. 1; col.7; line 29-31).

Re Claim 22: Fink disclose apparatus wherein the processor (CPU) device is arranged to store the signals picked up by the ultrasound probe (6) all n time intervals dt, n lying in the range of 50 to 500. (See Fig. 1; col.6; line 12-16).

Re Claim 24: Fink discloses wherein the probe (6) and the vibrator (2) are arranged so that the displacement of the vibrator for generating the shear wave is not transmitted to the probe, (See Fig. 1; col.1; line 51-54).

Re Claim 25: Fink discloses analysis method, comprising analyzing skin by means of the apparatus according to claim 1, (See col. 1; line9-16).

Re Claim 26: Fink discloses a method comprising the step of processing signals coming from the ultrasound probe (6) so as to determine at least one value relating to a mechanical property (strain or cancerous) of the skin (See col.1; line 62- col.2 line 9).

Re Claim 27: Finks discloses method wherein mechanical property is selected from the group consisting of its Young's modulus, its shear modulus, and the propagation speed of the shear wave, (See col. 8; line 41-45).

Re Claim 31: Fink discloses method of evaluating a mechanical property of a region of the skin, and delivering, from the results of the analysis, information relating to said mechanical property (See Fig.1; col.8; line 45-50).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3, 4, 6-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink.

Re Claim 3: Although fink fails to specifically disclose a thickness of the coupling member enables the ultrasound waves to be focused in a given region of maximum depth below a surface

of the skin. , it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reasonable thickness for the coupling member, in order to be able to transmit the pulses through the skin and the thickness of the coupling member does not prevent of transmitting of the signal.

Re Claim 4: Although Fink fails to specifically disclose wherein the depth of skin region is less than or equal to 4 mm. it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the focal point less that 4 mm in order to have an accurate data of the epidermis and dermis section of the skin that contains the mechanical part of the skin.

Re Claim 6: Fink discloses to use the coupling member material in between the surface (3) and the vibrator (2) and ultrasound probe (6).
Although Fink fails to specifically disclose apparatus wherein the thickness of the coupling member lies in the range 10.6 mm to 14.4 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the location of the coupling material within the range of the focal length in order to be able to obtain the reflection of the pulses from the skin or the tissue under examination.

Re Claim 7: Fink discloses to use the coupling member material as viscoelastic material.
Although Fink fails to specifically disclose apparatus wherein the coupling member is in the form of a disk of viscoelastic material. It would have been obvious to one of ordinary skill in the

art at the time the invention was made to use a disk shape container in order to for the coupling material to form a disk that matches the annular shape of the vibrator and the ultrasound probe.

Re claim 8: Although Fink fails to specifically disclose a holing ring with an inwardly rim to hold the coupling member against the skin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a holding device such as a ring with an inwardly rim, that keeps the coupling member steady against the skin in order to successfully transmit the pulses that are traveling trough the coupling member to reach the focal point on the tissue under examination.

Re claim 11 and 12: Although Fink specifically does not disclose apparatus wherein the contact surface presents circular symmetry about the axis, it is obvious to the one ordinary skill in the art at the time of invention was made to contact surface presents circular symmetry about the axis when the transmitting and receiving transducers are located symmetrically, then the system will appear to be aligned even if a rotation of 120.degree. in either direction takes place. This potential error can be avoided by, for example, using an asymmetric arrangement of the transducers which is considered by Fink or the circular or cylindrical symmetry about the axis) (see Fig. 1; col. 5; line 61 – col. 6; line 5).

9. Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink in view of Adachi (US 2002/0007118). The teachings of Fink have been discussed above.

Re Claim 5: However, Fink fails to disclose or fairly suggest apparatus wherein a focal length of the ultrasound probe lies in the range 10.4 mm to 15.6 mm.

Adachi teaches that a relation between the focal length and an actual processing curvature radius of the acoustic lens for 5 MHz and 10 MHz. And further shows that for a focal length to be 16 mm a 10 MHz frequency will be applied (See paragraph [00075]).

Therefore, in view of Adachi, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a 16 mm focal length in order to adjust a focus (focal point) in the same position.

10. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink in view of White (US 3,76,193). The teachings of Fink have been discussed above.

Re Claim 9: However, Fink fails to disclose or fairly suggest apparatus including a frame to which the vibrator and the probe are secured, wherein the frame enables the apparatus to be positioned so that the axis is substantially perpendicular to a surface of the skin.

White teaches a microscope lens supporting structure, wherein several lenses parallel to each other are connected in a vertical position with the support of a frame that connects lenses together (See Fig 2; col. 2; line 26-54)

Therefore, in view of White, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a frame to connect several devices in body of one apparatus in order to align the examining device on a vertical line perpendicular to the examining surface to reduce the length of pulses that are suppose the reach the focal point within the tissue

under examination.

10. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink in view of Kim (US 6656116). The teachings of Fink have been discussed above.

Re Claim 19 and 20: However, Fink fails to disclose or fairly suggest an apparatus wherein the processor device is arranged to deliver information relating to a state of the skin, by comparing a measured value with a reference value.

Kim teaches the controller 50 compares the stored reference value with the data received from the digital signal processor 40 and perceives a physical and emotional state using the result of the comparison. Here, the reference value is an average value of the bio-signals of general persons (See col. 4; line 65 to col. 5 line 1-50).

Therefore, in view of Kim, it would have been obvious to one of ordinary skill in the art at the time the invention was made to compare the received data with the reference in order to evaluate the properties of the under review tissues (skin) with the normal tissue as reference. It is obvious that this property could be degree of aging.

11. Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink in view of Koestner (US 5,139,020). The teachings of Fink have been discussed above.

Re Claim 23: However, Fink fails to disclose or fairly suggest Apparatus wherein dt lies in the range of 2.2 ms to 0.8 ms.

Koestner teaches one millisecond duration for pulses from the burst timer to be triggered in order transmit a pulse (See col. 4; line 65 to col. 19 line 25-40).

Therefore, in view of Koestner, it would have been obvious to one of ordinary skill in the art at the time the invention was made to transmit the pulses for evaluation with millisecond range in order to have a precise and more continues data, close to the real time examination.

12. Claims 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fink in view of Bonnefous (US 2002/0010398). The teachings of Fink have been discussed above.

Re Claim 28: However, Fink fails to disclose or fairly suggest a method wherein the phase lag of the shear wave is calculated as a function of the depth.

Bonnefous teaches an ultrasonic diagnostic imaging method for determining propagation parameters of transient shear wave front, comprising steps of forming transient shear waves in a tissue, acquiring ultrasonic image data of the tissue, along image lines, during a time delay for a transient shear wave front to propagate over a depth (z) in a tissue (See paragraph [0007]).

Therefore, in view of bonnefous, it would have been obvious to one of ordinary skill in the art at the time the invention was made to calculate the shear phase as a parameter of shear wave with respect of the depth of the wave in the tissue in order to complete the data related to the properties of the skin under examination.

13. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink in view of Mourad (US 2002/0095087). The teachings of Fink have been discussed above.

Re Claim 29: However, Fink fails to disclose or fairly suggest A method wherein a state of the skin is determined by comparing a value for Young's modulus resulting from analyzing the skin with reference values.

Mourad teaches the instrument compares the phase of emitted and received waves and alters the frequency of the next stimulus. (See paragraph [0033]) and further he teaches that this diagnostic probe may be used to detect the acoustic emission from the vibrated tissue. The amplitude of the acoustic emission is related to the tissue stiffness, or the Young's modulus, or shear modulus, of the target tissue, [See paragraph 0192].

Therefore, in view of Mourad, it would have been obvious to one of ordinary skill in the art at the time the invention was made to compare the values related to the Young's modulus or shear modulus with some reference in order to evaluate the skin and further adjust the parameter of future shear waves that is going to be transmitted.

Re Claim 30: However, Fink fails to disclose or fairly suggest a method wherein said state of the skin is a degree of aging of the skin.

Mourad teaches using ultrasound interrogation pulses, preferably in a scatter or Doppler detection mode and based on this data, tissue properties are assessed, characterized and monitored

Therefore, in view of Mourad, it would have been obvious to one of ordinary skill in the art at the time the invention made to combine the shear wave and the ultrasound pulses in order to find the characterization of the tissue under examination (skin). One of these characterization or properties could be state of aging that has direct relation with the elasticity of the tissue known to one ordinary skill in the art.

14. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink in view of Dikstein (US 4,206,769). The teachings of Fink have been discussed above.

Re Claim 32 and 34: However, Fink fails to disclose or fairly suggest method of determining the effectiveness of treatment that has action on a mechanical property of the skin, the method comprising: performing a first evaluation of said mechanical property; performing the treatment; and after the treatment, performing a second evaluation of said mechanical property, at least one of the first and second evaluations.

Dikstein teaches an objective method of measurement is provided, which makes possible to evaluation of the elasticity of human skin in vivo before and after application of certain cosmetic preparations, thus providing both an objective test for the efficacy of such preparations and for their effect on the individual treated with same (See col.1; line 20-25).

Therefore, in view of Dikstein, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine two stage of evaluation with treatment operation in order to test the qualitatively and quantitatively elasticity of tissues before and after a treatment.

Re Claim 33: However, Fink fails to disclose or fairly suggest A method of treating a region of a human body, the method comprising: evaluating a mechanical property of the skin in said region by implementing the method according to claim 31; and performing treatment that has action on said property in the light of the result of the evaluation.

Dikstein teaches an objective method of measurement is provided, which makes possible to evaluation of the elasticity of human skin in vivo before and after application of certain cosmetic preparations (See col. 1; line 20-25).

Therefore, in view of Dikstein, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the shear wave test in order to obtain information for evaluation and further perform a treatment if necessary.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sarvazyan discloses Method and apparatus for elasticity imaging; Adachi discloses ultrasonic wave transducer system and ultrasonic wave transducer; Ribault discloses frequency adjustment in high intensity focused ultrasound treatment apparatus; Marchitto discloses irradiation enhanced permeation and collection; Andrus discloses apparatus and method for transurethral focussed ultrasound therapy.; sommeschin discloses ultrasonic positioning;

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jong-Suk (James) Lee can be reached on 571-272-7044. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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2/05/2007

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